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10/529,009	03/24/2005	Kenji Soejima	081356-0237	4640

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,009	SOEJIMA ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *8 and 25-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/5/06&3/24/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-33 are pending.

2. Applicant's election without traverse of Group I, claims 1-24 drawn to an antibody against a protein or peptide of ADAMST-13 and SEQ ID NO: 1 as the species, filed on 11/12/07, is acknowledged.

3. Claims 8 (non-elected species) and 25-33 (non-elected Groups) are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. Claims 1-7 and 9-24 are under examination as they read on an antibody against a protein or peptide of ADAMST-13 and SEQ ID NO: 1 as the species.

5. Applicant's IDS, filed 4/05/06 & 03/24/05, is acknowledged.

6. Claims 10-11, 13-19 and 22-24 are objected to under 37 CFR § 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim.

7. 35 U.S.C. § 101 reads as follows:

> *"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".*

8. Claims 1-7, 9-11 and 13-14 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

> Claims 1-7, 9-11 and 13-14, as written, do not sufficiently distinguish over autoantibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

10. Claims 3-7 and 9-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) "Represented by" in claims 3-4, 20, implies *any member* of a genus that is "represented by" the SEQ ID NO: 1. Such language fails to establish the metes and bounds of amino acid sequence encompassed by the instant claim language; therefore the claim is indefinite.

B) The "antibody prepared by transfecting an expression vector capable of expressing said polypeptide chain directly into an animal" in claim 9 is ambiguous. It is unclear how the "animal" would take up the vector and what mechanism is involved. It is not clear how the vector would be transfected directly into an animal.

C) The recitation "and a gene encoding said antibody" in claims 11-12, is ambiguous. The preamble of the claims recite an antibody, it is unclear how the antibody now becomes "an antibody and a gene".

D) The term "culturing *in vivo*" in claim 22 is ambiguous. It is not clear how the skilled artisan would make an *in vivo* culture. It is not clear what controlled conditions required for *in vivo* growth of the cells.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the hybridoma that produce the WH10, WH63.1, WHS40.3, Pep4-34.1, WH2-22-1A, WH2-1-1, WH2-11-1, Pep6-6A and Pep4-5B-1 antibodies are required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, a deposit of the hybridoma, which produces this antibody, may satisfy first paragraph. See 37 CFR 1.801-1.809.

If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hybridoma has been deposited under the Budapest Treaty and that the hybridoma will be

irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample *or for the enforceable life of the patent whichever is longer*. See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

13. Claims 1-7 and 9-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated antibody against ADAMTS-13 of SEQ ID NO: 1, a method of making and a composition thereof and the specific hybridoma produce by the specific cells (after deposit is satisfied), does not reasonably provide enablement for the antibodies claimed in claims 1-7 and 9-24. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There is insufficient guidance and direction as to make and use antibodies against any "modified amino acid sequence of ADAMTS-13" in which one or several amino acids are deleted, substituted or added or a partial sequence of any one of said amino acid sequences" wherein ADAMTS-13 "derived from a primate or rodent" or the modification in claims 3, 5, 6, or a "pharmaceutical composition".

The claims require antibody to bind to different polypeptides of ADAMTS-13. However, the present specification fails to provide sufficient disclosure of amino acid fragments that maintain the structural and functional properties of the ADAMTS-13 activity set forth in SEQ ID NO:1, wherein the fragment is immunogenic, or modified sequence of SEQ ID NO:1 which include numerous changes and variation. The specification does not provide sufficient guidance as to which of the amino acids may be changed while ADAMTS-13 functional activity is retained.

The one of the uses of the claimed polypeptide is to make antibody then any change in the polypeptide of SEQ ID NO: 1 would affect the binding specificity of the antibody. Colman *et al* in Research in Immunology (145(1):33-36, 1994) teach single amino acid changes in an antigen can effectively abolish antibody antigen binding. Abaza *et al* in Journal of Protein Chemistry (11(5):433-444, 1992) teach that single amino acid substitutions outside the antigenic site on a protein effect antibody binding. Further, Lederman *et al* in Molecular Immunology (28:1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). Additionally, Li *et al* in PNAS (77:3211-3214, 1980) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document).

Because of this lack of guidance, an undue experimentation would be required to determine which modifications would be acceptable to retain occluding structural and functional activity, and the fact that the relationship between the sequence of a protein/peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it would require an undue amount of experimentation for one of skill in the art to arrive at the claimed modifications, fragments or peptides of SEQ ID NO:1 encompassed by the claimed invention.

Also, at issue is whether or not the claimed composition would function as pharmaceutical composition. In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the pharmaceutical composition as claimed, and absence of working examples providing evidence which is reasonably predictive that the claimed pharmaceutical composition are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a reasonable expectation of success.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

14. Claims 1-7, 9-11, 13-17 and 19-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of an isolated antibody against ADAMTS-13 of SEQ ID NO: 1, a method of making and a composition thereof and the specific hybridoma produce by the specific cells (after deposit is satisfied).

Applicant is not in possession of the antibodies claimed in claims 1-7, 9-11, 13-17 and 19-24.

Applicant has disclosed only amino acid of SEQ ID NO: 1; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between

function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claim 1-7, 9-11, 13-17 and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/042441 A3.

The WO `441 publication teaches anti-vWF-cp polypeptide antibodies (see page 1, lines 10-12 and published claims 19-20, in particular). The `441 publication teaches antibodies against the peptide AAGGILHLELLV (See Example 5 on page 38 and published SEQ ID NO: 1 in particular). The antigen AAGGILHLELLV has 100% sequence identity with amino acids 75-86 of claimed SEQ ID NO: 1. The referenced antibodies would bind claimed ADAMTS-13 protein. The antigen peptide is the located at the N-terminus of the metaloprotease. Further, the referenced antibody should bind to bind to a modified amino acid sequence of ADAMTS-13. Since the antibody is made against the metalloprotease domain the referenced antibody would inhibit or neutralize the enzyme activity of a protein. Furthermore, the referenced vWF-cp of published SEQ ID NO: 5 is 100% identical to claimed ADMSTS-13 of claimed SEQ ID NO:1 (see fig. 1, and published SEQ ID NO: 5 in particular). The `441 publication teach thath the anti-vWF-cp polypeptide antibodies which can be produced by immunization of an animal with a polypeptide of the inventions and isolation of anti-vWF-cp polypeptide antibodies from the animal (see page 19, lines 21-25, and page18, lines 29-32 in particular). The `441 publication further teaches polyclonal, monoclonal, chimeric, single chain or humanized antibodies (see page 19, lines 1-3 in particular). The `441 publication teaches the domain structure organization of the vWF-cp (see figs. 5 and 6). The `441 publication teaches an antibody coated ELISA plates

(Kits) system comprising the claimed antibody. The '441 publication refers to immunofluorescence an related staining techniques (see page 39 in particular).

The '441 publication teach a method of preparing that the antibody by immunizing a 3 months old BALB/C mice with the peptide. Also, the '441 publication teaches anti-peptide antibodies producing hybridoma cell lines (see Example 5, in particular).

Claim 2 is included be the referenced antibodies would bind to ADAMTS-13 derived from a primate or rodent in the absence of evidence to the contrary.

Claims 5-6 is included because the claims recite the same products and the intended uses do not carry patentable weight per se and the claims read on the active or essential ingredients of the anti-ADAMTS-13 antibodies.

Claim 9 is included because antibody is antibody irrespective of how it is made. The patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), MPEP 2113.

The reference teachings anticipate the claimed invention.

17. Claim 1-7, 9-11, 13-15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Chung and Fujikawa (Biochemistry, 41(37): 11065-11070, September 17, 2002).

Chung and Fujikawa teach autoimmune antibodies to the VWF cleaving protease (ADAMTS-13) (see page 11066, 2nd col., 1st ¶ and page 11069, under *Perspective* in particular). Chung and Fujikawa teach that the nature and abundance of the degradation fragments were detected by antibodies in Western blotting. Residual VWF binding to collagen was detected by an enzyme-linked immunosorbant assay (Kit) using anti-VWF antibodies. Monoclonal antibodies specific for an epitope C-terminal to the cleavage site were used to capture VWF molecules, and loss of N-terminal fragments resulting from digestion with ADAMTS-13 was detected by a decreased level of binding of ^{125}I-labeled monoclonal antibodies specific for the N-terminus of the VWF subunit (see page 11067-11068 under *Activity and Specificity* in particular).

Claim 2 is included be the referenced antibodies would bind to ADAMTS-13 derived from a primate or rodent in the absence of evidence to the contrary.

Claims 5-6 is included because the claims recite the same products and the intended uses do not carry patentable weight per se and the claims read on the active or essential ingredients of the anti-ADAMTS-13 antibodies.

Claim 9 is included because antibody is antibody irrespective of how it is made. The patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), MPEP 2113.

The reference teachings anticipate the claimed invention.

18. Claim 1-7, 9-10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Furlan et al, Blood. 1996 May 15;87(10):4223-34.

Furlan et al teach peroxidase- labeled rabbit anti-human-vWF (P226) antibody (see page 4224, under *Materials, and uder SDS-agarose gel electrophoresis* in particular). Furlan et al further teach rabbit antiserum against human vWF (RAHu/FVIII) antibodies (see page 4224, under *Immunoblotting of reduced vWF* in particular).

Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibody does not bind to the SEQ ID NO:1 recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

19. Claim 1-7, 9-10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1 152 0055 A1 (April 2001).

The `055 publication teaches and claims anti-ADAMTS-M antibodies, wherein the antibody is polyclonal or monoclonal and can be prepared using techniques standard in the art (see published claim 8, SEQ ID NO: 2 and page 11, under *Antibodies to ADAMTS-M* in particular). It is noted that published ADAMTS-M of SEQ ID NO: 2 shares 97.4% sequence identity with claim SEQ ID NO:1, wherein published SEQ ID NO:2 has a gap (several amino acid deletion) at positions 1156-1190 of claimed SEQ ID NO: 1. An antibody to the shorter ADAMTS-M of published SEQ ID NO: 2 would bind to the longer sequence of claimed SEQ ID NO: 1.

The reference teachings anticipate the claimed invention.

20. Claim 1-7, 9-10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Zheng et al, J. Biol. Chem. 276:41059-41063(2001).

Zheng et al teach the use of anti-VWFCP antibodies to assess VWFCP deficiency wit TTP (see page 41062 last ¶ in particular). Referenced VWFCP of Fig. 1 shares 100% sequence homology with claimed SEQ ID NO:1.

The reference teachings anticipate the claimed invention.

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

22. Claims 1-7, 9-11, 13, 16-17 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheng et al in view of.

Zheng et al teachings have been discussed, supra. Further, Zheng et al teach identified VWFCP as a member of the ADAMTS family of metalloproteases and designated ADAMTS13. VWFCP consist of 1427 amino acid residues and has a signal peptide, a short propeptide terminating in the sequence RQRR, a reprolysin-like metalloprotease domain, a disintegrin like domain, a thrombospondin-1 repeat, a Cys-rich domain, an ADAMTS spacer, seven additional thrombospondin-1 repeats, and two CUB domains. Furthermore, Zheng et al teach that VWFCP apparently is made as a zymogen that requires proteolytic activation, possibly by furin intracellularly. Further, sites for Zn^{2+} and Ca^{2+} ions are conserved in the protease domain. The Cys-rich domain contains an RGDS sequence that could mediate integrin-dependent binding to platelets or other cells. Alternative splicing gives rise to at least seven potential variants that truncate the protein at different positions after the protease domain. Alternative splicing can have functional significance, producing proteins with distinct abilities to interact with cofactros, connective tissue, platelets and von Willebrand factor (see abstract, Fig. 1, Fig. 1, and Fig. 3 in particular). Finally, Zheng et al teach that the characterization of the VWFCP (ADAMTS13) will facilitate the investigation of important biochemical and medical questions and can lead to the development of more specific treatment for TTP (see page 41062, last ¶ in particular).

The claimed invention differs from the reference teachings only by the recitation of an isolated antibody which specifically binds to ADAMST-13, a partial sequence of ADAMTS-13, specific portion ; and a method of making a monoclonal/polyclonal antibody comprising immunizing an animal with said polypeptide.

However, it has been held that once the antigen of interest is selected, the use of that antigen in the known method of Kohler and Milstein will result in the expected hybrid cell lines and the specific monoclonal antibodies. Ex parte Erlich, 3 USPQ2d 1011, 1015 (BPAI 1986).

Campbell teaches that it is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (see page 3 figure 11.1 in particular). One field of research in which monoclonal antibodies may prove of particular value is in the study of chromosomal proteins. The search for those chromosomal proteins which are responsible for determining cell phenotype has been particularly long and comparatively fruitless and monoclonal antibodies are ideal tools for the dissection of the complex mixture of proteins. As hybridoma production becomes a more routine laboratory technique (see page 29 and 30 under Basic research in particular).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to to make a monoclonal antibody as taught by Campbell against the polypeptides of SEQ ID NO: 1 taught by the Zheng et al reference.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because it was customary at the time the invention was made to make monoclonals against any new macromolecule as taught by Campbell and to facilitate the investigation of important biochemical and medical questions which can lead to the development of more specific treatment for TTP taught by the Zheng et al reference.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this

application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 9-11, 13-15 and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-7 of copending Application No. 10/549317. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are expressly claiming the same subject mater, although they differ in scope. Specifically, pending claims 5-7 of the `317 application and instant claims are directed to antibodies capable of binding to a polypeptide or a peptide fragment derived from the ADAMTS-13 polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. No claim is allowed.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 3, 2008

Maher Haddad

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Primary Examiner
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